

AMOXYCILLIN SANDOZ®

Amoxicillin Trihydrate capsules and suspension

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Amoxicillin Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Amoxicillin Sandoz against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT AMOXYCILLIN SANDOZ IS USED FOR

The name of your medicine is Amoxicillin Sandoz. It contains the active ingredient amoxicillin trihydrate.

Amoxicillin Sandoz is an antibiotic used to treat infections in different parts of the body caused by bacteria.

Amoxicillin Sandoz belongs to a group of antibiotics called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

This medicine can also be used to prevent certain infections.

Amoxicillin Sandoz will not work against infections caused by viruses such as colds or the flu.

Your doctor may have prescribed Amoxicillin Sandoz for another reason. Ask your doctor if you have any questions about why Amoxicillin Sandoz has been prescribed for you.

Amoxicillin Sandoz is available only with a doctor's prescription.

Amoxicillin Sandoz is not addictive.

BEFORE YOU TAKE AMOXYCILLIN SANDOZ

When you must not take it

Do not take Amoxicillin Sandoz if:

- **you have an allergy to amoxicillin, any other penicillins or any of the ingredients listed at the end of this leaflet**
- **you have had a serious allergic reaction to any β -lactam antibiotics (e.g. penicillins, cephalosporins, carbapenem or monobactam). These are another group of antibiotics similar to penicillins.**

Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.

Do not take Amoxicillin Sandoz after the expiry date printed on the pack has passed.

Do not take Amoxicillin Sandoz if the packaging is torn or shows signs of tampering or if the medicine does not look right.

If you are not sure if you should start taking Amoxicillin Sandoz, contact your doctor.

BEFORE YOU START TO TAKE IT

Tell your doctor if:

1. **you have had any type of allergic reaction to any penicillin or cephalosporin medicines.**

You may have an increased chance of being allergic to Amoxicillin Sandoz if you are allergic to any penicillins or cephalosporins.
2. **you have any allergies to:**
 - any other medicines
 - any other substances such as foods, preservatives or dyes.
3. **you are pregnant or intend to become pregnant.**

Your doctor will discuss the possible risks and benefits of using Amoxicillin Sandoz during pregnancy.
4. **you are breast-feeding or intend to breast-feed.**

Amoxicillin Sandoz passes into breast milk. No detrimental effects for the breast-fed infant have been reported after taking amoxicillin. Amoxicillin can be used during breast-feeding. However, breast-feeding must

be stopped if gastrointestinal disorders (diarrhoea, candidosis or skin rash) occur in the new born. Your doctor will discuss the risks and benefits of taking Amoxicillin Sandoz when breast-feeding.

5. you have or have had any medical conditions, including:

- asthma
- kidney problems
- liver problems
- lymphatic leukaemia
- glandular fever
- diabetes
- seizures history
- stomach or bowel problems
- a history of allergic problems, including hayfever.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Amoxicillin Sandoz. These include:

- medicines used to treat gout (e.g. probenecid or allopurinol)
- digoxin, a medicine used to treat heart failure
- medicines used to prevent blood clots from the coumarin class (e.g. warfarin)
- methotrexate, a medicine used to treat arthritis and some types of cancers
- oral contraceptives (birth control pills)
- other antibiotics (e.g. tetracycline).

These medicines may be affected by Amoxicillin Sandoz or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Talk to your doctor about the need for an additional method of contraception while taking Amoxicillin Sandoz.

Some antibiotics may decrease the effectiveness of some birth control pills.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Amoxicillin Sandoz.

HOW TO TAKE AMOXYCILLIN SANDOZ

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you the dose of Amoxicillin Sandoz you will need to use each day. This depends on the condition being treated and whether any other medicines are being used.

In adults the usual dosage is 250-500mg three times daily.

In children, the usual dosage is 125-250 mg three times daily and may vary depending on the weight of your child.

How to take it

Amoxicillin Sandoz Capsules:
Take the capsules with a glass of water.

Amoxicillin Sandoz Suspension:
The suspension will be prepared by your pharmacist who checks the seal prior to reconstitution. Shake the bottle well and accurately measure the dose with a measuring spoon. Your pharmacist will explain how

many millilitres of suspension will be needed to receive the correct dose.

Do not use the reconstituted suspension if the colour is not off-white.

Shaking the bottle and using a measuring spoon will make sure that you get the correct dose.

When to take it

In order for Amoxicillin Sandoz to be most effective, it should be taken at regular times through the day. For example, if you are taking it three times a day, take a dose every 8 hours.

Your doctor or pharmacist can advise you on a dosing schedule if you are unsure.

Amoxicillin Sandoz can be taken with or without food.

How long to take it

Continue taking Amoxicillin Sandoz until you finish the capsules or suspension, or for as long as your doctor recommends.

Keep taking this medicine for the full course of treatment, even if you begin to feel better after a few days.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

Check with your doctor if you are not sure how long you should be taking Amoxicillin Sandoz.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Amoxicillin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Amoxicillin Sandoz, you may experience symptoms such as diarrhoea, nausea, vomiting or stomach cramps.

WHILE YOU ARE TAKING AMOXYCILLIN SANDOZ

Things you must do:

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea tell your doctor or pharmacist immediately.

Do this even if it occurs several weeks after Amoxicillin Sandoz has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore white mouth or tongue while taking or soon after stopping Amoxicillin Sandoz, tell your doctor. Also tell your doctor

if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Amoxicillin Sandoz allows fungi to grow and the above symptoms to occur. Amoxicillin Sandoz does not work against fungi.

Tell your doctor if you become pregnant while taking Amoxicillin Sandoz.

If you have to test your urine for sugar while you are using Amoxicillin Sandoz, make sure your doctor knows which type of test you use.

Amoxicillin Sandoz may affect the results of some of these tests.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Amoxicillin Sandoz.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Amoxicillin Sandoz.

Things you must not do

Do not stop taking your medicine because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints, unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Amoxicillin Sandoz affects you.

Amoxicillin Sandoz may cause tiredness or dizziness in some people. Make sure you know how you react to Amoxicillin Sandoz

before you drive a car, operate machinery or do anything else that may be dangerous if you are affected.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Amoxicillin Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. The most commonly reported adverse drug reactions (ADRs) are diarrhoea, nausea and skin rash.

Ask your doctor or pharmacist to answer any questions you may have.

WHILE YOU ARE TAKING AMOXYCILLIN SANDOZ

Tell your doctor if you notice any of the following and they worry you:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina or discharge
- diarrhoea
- feeling sick (nausea), vomiting
- soreness of the mouth or tongue
- discoloration of the teeth (especially with the suspension). Usually the discoloration can be removed by teeth brushing
- headache, tiredness.

These side effects are usually mild.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- signs of anaemia such as looking pale, short of breath when exercising, dizziness
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal
- dark coloured urine or blood in the urine
- passing more or less urine than is normal for you.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Amoxicillin Sandoz and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- any skin rash, itching or hives or blistering or peeling of the skin
- wheezing, shortness of breath or difficulty breathing
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- aching or swollen joints
- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel.

Therefore, you may need urgent medical attention. However, these side effects are rare.

Do not take any diarrhoea medicine without first checking with your doctor.

Other side effects not listed in this leaflet may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

AFTER USING AMOXYCILLIN SANDOZ

Storage

Keep your medicine in its original container, in a safe place out of reach of children.

Do not store your medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Do not leave your medication in a car or on a window sill.

Keep the capsules or the suspension in a cool dry place below 25°C.

Discard any unused suspension after 14 days or after the expiry date placed by your pharmacist on the label of the bottle during the preparation of the suspension.

Disposal

If your doctor tells you to stop taking Amoxicillin Sandoz, or the medicine has passed its expiry date, ask your pharmacist what to do with any medicine left over.

PRODUCT DESCRIPTION

What it looks like

Amoxicillin Sandoz Capsules - opaque yellow hard gelatin capsules.

Available in blisters packs of 20 capsules.

Amoxicillin Sandoz Suspension - After mixing, the suspension is white to slightly yellowish.

Available in 100 mL bottle.

Ingredients

Amoxicillin Sandoz Capsules contain either 250 mg or 500 mg of amoxicillin (as amoxicillin trihydrate).

The capsules also contain:

- magnesium stearate
- microcrystalline cellulose
- gelatin
- iron oxide yellow C177492
- titanium dioxide.

Amoxicillin Sandoz Suspension contains either 125 mg or 250 mg of amoxicillin (as amoxicillin trihydrate) per 5 mL.

The suspension also contains:

- anhydrous citric acid
- sodium benzoate
- aspartame
- purified talc
- guar gum
- sodium citrate anhydrous
- silicon dioxide
- lemon flavouring
- orange flavouring
- peach-apricot flavouring.

This medicine does not contain lactose, sucrose, or gluten.

Supplier

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

This leaflet was revised in August 2020.

Australian register numbers

250 mg Capsules: AUST R 63332
(blisters)

500 mg Capsules: AUST R 63333
(blisters)

125 mg/5 mL powder for oral
suspension: AUST R 93721
(bottles)

250 mg/5 mL powder for oral
suspension: AUST R 93720
(bottles)